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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,515	12/31/2003	Mineo Yamakawa	042390.P15614	9237

25227 7590 02/09/2007
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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/750,515

Applicant(s)

YAMAKAWA ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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The amendment filed November 13, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to paragraph 0111 contains new Matter. Applicants do not point to basis in the application as filed for the insertion of "10/748,336" into line 3 of paragraph 0111. Applicant is required to cancel the new matter in the reply to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "detectable non-encoding feature" (claims 1, 15, 16, 20, 24, 29, and 33) is vague and indefinite because the instant application does not distinguish between a detectable non-encoding feature and an undetectable non-encoding feature. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 3, item (b)). Applicants' assertion (response filed November 13, 2006, page 12, paragraphs 2-4) is not convincing. No specific definition of the term is seen in paragraph 0017 of the specification. Applicants' argument that "non-encoding feature" cannot be separated from "detectable non-encoding feature" is not persuasive because applicants give no reason for their conclusion the meaning as defined in the specification would be "eviscerated". Since applicants have not pointed to a specific definition, there is nothing to "eviscerate". Furthermore, it is not understood what is meant to "eviscerate" a meaning.
- (b) The recitation of "non-encoding" (claims 1, 15, 16, 20, 24, 29, and 33) is vague and indefinite because it is not understood what is meant by the term. This rejection is

repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 3, item (c)). The discussion in (a) above is incorporated here.

- (c) The recitation of "substantially represents all possible complementary sequences" (claim 2) is vague, indefinite, and incomplete because the metes and bounds of "substantially" are not clear and because it is not clear whether only A, G, C, and T are to be used to the exclusion of any other nucleotides in the construction of the sequences. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 3, item (e)). Applicants' arguments (response filed November 13, 2006, paragraph bridging pages 12-13) are not convincing. First, applicants have not addressed the issue of the term "substantially". Second, no specific definition is seen in paragraph 0074 (cited by applicants) or in paragraph 0075 (not cited by applicants). Applicants have not indicated whether only A, G, C, and T are to be used to the exclusion of any other nucleotides in the construction of the sequences. Since paragraph 0075 mentions the use of analogs of RNA and DNA, the claim is construed to include the use of nucleotide analogs. Since the application does not indicate which analogs are considered to be complements of one another or of A, G, C, or T, the metes and bounds of the claim are unclear.
- (d) The recitation of "checksum barcode segment" (claim 18) is vague and indefinite because it is not understood what is meant by the term within the context of the claim. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 4, item (j)). Applicants' argument (response filed November 13, 2006, page 13, last full paragraph) is not convincing. Applicants refer to material on a website, which material is not in the record and has, accordingly, not been considered. The remainder of applicants' argument merely asserts that the meanings of the terms are self-explanatory. This latter argument fails to persuade.

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- (e) The recitation of "single molecule level surface analysis method" (claim 20) is vague and indefinite because the term is not defined in the application and has no art-recognized definite meaning. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 4, item (k)). Applicants' argument (response filed November 13, 2006, paragraph bridging pages 13-14) is not convincing. Applicants refer to material on a website, which material is not in the record and has, accordingly, not been considered. Applicant further merely asserts that one of skill in the art would know the metes and bounds of the claim. This assertion is not convincing in the absence of an explanation.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 10-15, 17, 18, 28, and 30-32 of copending Application No. 10/251,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious for one of ordinary skill in the art to possess the compositions of claims 20-28 of the instant application in view of the methods of using compositions that embrace the compositions of claims 20-28 of the instant application as outlined in claims 1, 4, 5, 10-15, 17, 18, 28, and 30-32 of copending application Serial No. 10/251,152.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-15, 29-32, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-14, 28, and 30-32 of copending Application No. 10/251,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application Serial No. 10/251,152 embrace claims 1-15, 29-32, and 35 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-32 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-28 of copending Application No. 10/667,004. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 25-28 of Serial No. 10/667,004 embrace claims 20-32 and 35 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 9, and 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, and 21 of copending Application No. 10/667,004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10/667,004 embrace claims 1-4, 9, and 12-14 of the instant application. Applicants' arguments (response filed November 13, 2006, page 16) are not persuasive because the language of the claims is so broad, vague, and indefinite that the claims of Serial No. 10/667,004 embrace those of the instant application. A non-encoding feature can be any part of the probe-nanocode composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 20-32 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/077,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious for one of ordinary skill in the art to possess the compositions and systems of claims 20-32 and 35 of the instant application in view of the methods of using compositions that embrace the compositions of claims 20-32 and 35 of the instant application as outlined in claims 1-18 of Serial No. 11/077,577. In addition, the compositions and systems of claims 19-27 of Serial No. 11/077,577 embrace claims 20-32 and 35 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 9, and 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 11 of copending Application No. 11/077,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 11/077,577 embrace claims 1-4, 9, and 12-14 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-36 are rejected under 35 U.S.C. 102(e) as being anticipated by either one of Chan et al (U.S. Patent Application Publication 2004/0058328) or Chan et al (U.S. Patent Application Publication 2004/0126820). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, paragraph bridging pages 6-7). Applicants' argument (response filed November 13, 2006, page 19) is not persuasive because the claim language is so broad, vague, and indefinite that a "detectable non-encoding feature" can be virtually any part of the probe-nanocode composition mentioned in the claims.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e).

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This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan et al (U.S. Patent Application Publication 2005/0208554). The claimed invention is disclosed in the reference.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 20-24 and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Han et al (Nature Biotechnology 19: 631 (2001)). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, page 7, first full paragraph). Applicants' arguments (response filed November 13, 2006, pages 19-20) are not convincing because the claim language is so broad, vague, and indefinite that a "detectable non-encoding feature" can be virtually any part of the tagged probe of Han et al. Applicants' argument regarding the intended purpose for the detectable non-encoding feature as a quality control check is not persuasive because the compositions are the same irrespective of their intended uses. The intended use is not a limitation on the composition *per se*.

Claims 1-4, 9-15, 20-23, 26, 28-32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al (U.S. Patent No. 6,361,944) in view of Nygren et al (U.S. Patent No. 6,060,237). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed December 23, 2005, paragraph bridging pages 7-8). Applicants' arguments (response filed November 13, 2006, pages 20-21) are not convincing because the claim language is so broad, vague, and indefinite that a "detectable non-encoding feature" can be virtually any part of the probe of Mirkin et al. Applicants' argument in connection with the intended purpose for the detectable non-encoding feature as a quality control check is not persuasive because the compositions are obvious irrespective of their intended uses.

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(*e.g.*, claims 20-23, 26, and 28-32). Applicants' arguments in connection with the method claims (claims 1-4 and 9-15) being unobvious because of the detectable non-encoding feature's intended purpose being a quality control check are not persuasive because the claims do not contain a positive quality control check step.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

1/31/07